



# Cardio Policy:

## Subcutaneous ICD Device Implantation and Removal

<b>POLICY NUMBER</b> UM CARDIO_1389	<b>SUBJECT</b> Subcutaneous ICD Device Implantation and Removal	<b>DEPT/PROGRAM</b> UM Dept	<b>PAGE 1 OF 3</b>
<b>DATES COMMITTEE REVIEWED</b> 02/12/20, 01/13/21, 07/14/21, 07/13/22	<b>APPROVAL DATE</b> July 13, 2022	<b>EFFECTIVE DATE</b> July 29, 2022	<b>COMMITTEE APPROVAL DATES</b> 02/12/20, 01/13/21, 07/14/21, 07/13/22
<b>PRIMARY BUSINESS OWNER:</b> UM		<b>COMMITTEE/BOARD APPROVAL</b> Utilization Management Committee	
<b>URAC STANDARDS</b> HUM v8: UM 1-2; UM 2-1	<b>NCQA STANDARDS</b> UM 2		<b>ADDITIONAL AREAS OF IMPACT</b>
<b>CMS REQUIREMENTS</b>	<b>STATE/FEDERAL REQUIREMENTS</b>		<b>APPLICABLE LINES OF BUSINESS</b> Commercial, Exchange, Medicaid

### I. PURPOSE

Indications for determining medical necessity for Subcutaneous ICD (S-ICD) device.

### II. DEFINITIONS

The S-ICD System is a Subcutaneous (under the skin) Implantable Cardioverter Defibrillator for people who are at risk of Sudden Cardiac Arrest. Unlike a transvenous ICD, where the leads are fed into the heart through a vein and attached to the heart wall, the leads for S-ICD is placed just under the skin and not in the heart, leaving the heart and veins untouched and intact. The pulse generator is implanted on the left side of the chest next to the rib cage, just under the arm. The lead is vertically positioned in the subcutaneous tissue of the chest, parallel to and 1-2 cm to the left sternal midline followed by a horizontal segment, at the level of the 6th rib, until it reaches the left anterior axillary line. The lead has an 8-cm shock coil, flanked by two sensing electrodes - the distal one positioned adjacent to the manubriosternal junction and the proximal one adjacent to the xiphoid process.

An appropriate diagnostic or therapeutic procedure is one in which the expected clinical benefit exceeds the risks or negative consequences of the procedure by a sufficiently wide margin such that the procedure is generally considered acceptable or reasonable care. The ultimate objective of AUC is to improve patient care and health outcomes in a cost-effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care - Median Score 7-9

May be Appropriate Care - Median Score 4-6

Rarely Appropriate Care - Median Score 1-3

### III. POLICY

**Indications for approving a request for medical necessity are:**

- A. S-ICD is appropriate in patients with congenital heart diseases or patients with no venous access who are unsuitable for transvenous ICD. **(AUC Score 8)<sup>2,3,4</sup>**
- B. S-ICD is appropriate in high risk cases of previous device infection, hemodialysis, chronic immunosuppression therapy immunodeficiencies, or artificial heart valves. **(AUC Score 8)<sup>2,3,4</sup>**
- C. S-ICD is appropriate in patients who are candidates for cardiac transplant. **(AUC Score 7)<sup>1,2,3</sup>**
- D. S-ICD is a reasonable choice in patients with Hypertrophic Cardiomyopathy where there is no indication for Anti-Tachycardia Pacing (ATP). **(AUC Score 7)<sup>1,2,3</sup>**
- E. S-ICD is a reasonable choice for Primary prevention of Sudden cardiac death in patients with ischemic/non ischemic dilated cardiomyopathy. **(AUC Score 7)<sup>1,2,3,4</sup>**
- F. Procedures for lead repositioning or replacement are appropriate in cases of lead complications involving inappropriate shocks, oversensing, or other specified lead failure. **(AUC Score 7)<sup>1,2,3,4,5</sup>**

**Limitations:**

- A. S-ICD is not indicated in patients with symptomatic bradycardia requiring permanent pacing.
- B. S-ICD is not indicated in patients with systolic heart failure and left bundle branch block and has indication for CRT.
- C. S-ICD is not indicated in patients with recurrent sustained monomorphic VT treatable with ATP.
- D. S-ICD is not indicated in thin patients with poor subcutaneous tissue and abnormalities of chest wall like pectus excavatum.

### IV. PROCEDURE

- A. In order to review a request for medical necessity, the following items must be submitted for review:
  - 1. Progress note that prompted request
  - 2. Echo or MUGA or Cardiac CATH for LV function.
  - 3. Previous Holter/Event/Loop recorder report
- B. Primary codes appropriate for this service: 33270-Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed, 33271-Insertion of subcutaneous implantable defibrillator electrode, 33272-Removal of subcutaneous implantable defibrillator electrode, 33273-Repositioning of previously implanted subcutaneous implantable defibrillator electrode

### V. APPROVAL AUTHORITY

- A. Review – Utilization Management Department
- B. Final Approval – Utilization Management Committee

## VI. ATTACHMENTS

- A. None

## VII. REFERENCES

1. Centers for Medicare & Medicaid Services -Proposed Decision Memo for Implantable Cardioverter Defibrillators (CAG-00157R4)
2. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death, Heart Rhythm (2017) doi: 10.1016/j.hrthm.2017.10.036.
3. Indranill Basu-Ray, et al. "Subcutaneous Versus Transvenous Implantable Defibrillator Therapy." JACC: Clinical Electrophysiology. Sep 2017, 496; DOI: 10.1016/j.jacep.2017.07.017
4. Robert C. Hendel MD, FACC, FAHA, et al. Appropriate use of cardiovascular technology: 2013 ACCF appropriate use criteria methodology update: a report of the American College of Cardiology Foundation appropriate use criteria task force. Journal of the American College of Cardiology. March 2013, Volume 61, Issue 12, Pages 1305-1317.
5. Olde Nordkamp LR, et al. The entirely subcutaneous implantable cardioverter-defibrillator: initial clinical experience in a large Dutch cohort. J Am Coll Cardiol 2012; 60:1933.
6. NCQA UM 2022 Standards and Elements.